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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,992	02/19/2003	Erica Lahav	D01/200	2589

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,992

Applicant(s)

LAHAV ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of "with the proviso that said enteric coating does not include HPMCP (hydroxypropyl methylcellulose phthalate)". However, this same material is included in the list of suitable enteric coating materials in Claim 7, in the first line on Page 23 of the instant application. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-10, 14, 15, 17-19, 21-25, 29, 30, 32, 33, 36, and 37 rejected under 35 U.S.C. 102(b) as being anticipated by Dietrich *et al.* (WIPO Publication No. WO 99/27917, English translation provided)

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All citations of the Dietrich *et al.* document will be made in reference to the enclosed English translation.

The Dietrich *et al.* patent discloses benzimidazole derivative compositions comprising a core and neutralized enteric coatings that are in direct contact with the core (See Page 7, Lines 1-10). Specific benzimidazole derivatives that are deemed suitable for the disclosed compositions include omeprazole, pantoprazole, lansoprazole, and salts thereof (See Page 7, Lines 12-15; and Example 3). Various materials may be used for the enteric coating, including cellulose acetate phthalate, cellulose acetate trimellate, and hydroxy propyl methyl cellulose succinate. Additives such as softeners may be added to these coatings (See Page 9, Lines 9-21). The enteric coating is preferably applied as an aqueous dispersion and treated with a base (See Page 10, Lines 13-20). Suitable bases that may be used to neutralize the enteric coating include sodium hydroxide and ammonium hydroxide (See Page 10, Line 21 to Page 11, Line 2). The resulting pH of the neutralized coating will usually range from 4 to 8, although high values are not considered to be disadvantageous (See Page 11, Lines 4-10; and Page 13, Line 10). The examples provided in the reference show instances where the cores may be formed by wet granulation or by coating the active ingredient over a neutral core, with the enteric coating applied directly over the core. Hydroxypropyl methylcellulose phthalate is not used in any of the examples provided (See Examples 1-4, and Examples 5 in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich *et al.* in view of Lundberg *et al.* (U.S. Patent No. 6,013,281) and Lee *et al.* (U.S. Patent No. 6,228,400 B1)

The relevant portions of the Dietrich *et al.* reference are detailed in the above rejection of Claims 1-3, 5, 7-10, 14, 15, 17-19, 21-25, 29, 30, 32, 33, 36, and 37 under 35 U.S.C. 102(b).

Limitations of composition claims that are drawn to how a composition or component of that composition is made are not given patentable weight. Claims 4 and 6, which recite such limitations are therefore considered obvious in view of the disclosure of the prior art.

Claims 11-13 and 26-28 contain limitations reciting a percentage value of the degree of neutralization of an enteric coating material. It is the position of the examiner that such properties are inherent in an enteric coating material of the prior art when the pH of an enteric coating is adjusted to a particular value using known methods. Therefore, these claims are considered to be obvious in view of the prior art.

Claim 35 is drawn to a step of formulating a drug core by direct compression. It is the position of the examiner that direct compression, being a technique well known in the prior art, is not critical to the success of the invention. The examiner shifts the burden onto the applicant in order make a showing of results that are unexpected in the purview of one of ordinary skill in the art.

The Dietrich *et al.* reference does not teach the use of citric acid esters or phthalic acid esters as plasticizers, nor does it teach the use of poloxamer in the disclosed formulations.

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The Lundberg *et al.* patent teaches enteric-coated compositions of benzimidazole derivatives (See Abstract; and Claim 1). Polymers suitable for use as enteric coatings in the disclosed compositions include cellulose acetate phthalate, cellulose acetate trimellate, and hydroxy propyl methyl cellulose succinate. Suitable plasticizers for use with these materials include citric acid esters and phthalic acid esters (See Column 7, Lines 27-53).

The Lee *et al.* patent teaches enteric-coated compositions of benzimidazole derivatives that further comprise an inert core and a drug emulsion layer over the core. The drug emulsion layer comprises the active ingredient and a non-ionic surfactant. Poloxamer 188 is named as a suitable surfactant for this purpose (See Column 5, Lines 5-41; and Example 1).

It would be obvious to one of ordinary skill in the art to combine the teachings Dietrich *et al.*, Lundberg *et al.*, and Lee *et al.* into the objects of the instant application. All three prior art references disclose enteric-coated compositions of benzimidazole derivatives, and are therefore pertinent for application against the instant claims. Although both the Lundberg *et al.* and the Lee *et al.* patents contain undesirable elements that the instant application seeks to overcome, it is the position of the examiner that certain portions of the prior art can still be used without introducing the drawbacks that the instant application seeks to avoid. Lundberg *et al.* is relied upon for the disclosure regarding suitable plasticizers for use with the disclosed enteric coatings, many of which are also cited in Dietrich *et al.* as being suitable for use as neutralized enteric coatings. It is the position of the examiner that one of ordinary skill in the art can use the plasticizers disclosed in Lundberg *et al.* in the neutralized coatings of Dietrich *et al.* with a reasonable expectation of success in forming stable benzimidazole derivative compositions. The Lee *et al.* patent is relied upon for the disclosure regarding the use of poloxamer in formulating

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drug cores. It is the position of the examiner that one of ordinary skill in the art can incorporate the use of poloxamers, as disclosed in Lee *et al.*, with the drug cores described in Dietrich *et al.* with a reasonable expectation of success in forming a neutral drug core, as part of a process in forming stable benzimidazole derivative compositions. Thus, the instantly claimed invention is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjoh
April 21, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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